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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/743,250

12/22/2003

Abdolmohamad Rostami

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,250

Applicant(s)

ROSTAMI ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the species election in the reply filed on August 29, 2006 is acknowledged. Applicant's arguments are persuasive. Therefore, the Examiner agrees to examine both of the species set forth in Claim 18, namely Experimental Autoimmune Encephalomyelitis and Experimental Autoimmune Neuritis. The Claims were examined on the merits taking each of the species into consideration.

Claims 14-19 are under examination.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

In the instant case, the abstract recites "novel" in line 1. It is suggested that the term "novel" be deleted from the language of the abstract. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel or new, since the scope of the invention no longer embraces what is considered "novel". Thus, the incorporation of the term "novel" into the language of the abstract is not appropriate. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the animal" in line 2. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by adding model after "animal".

Claim 14 recites the limitation "the chronic neuroinflammation" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation " the chronic neuroinflammation " in line 2. There is insufficient antecedent basis for this limitation in the claim.

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Claim 16 recites the limitation "the patient" in line 2. There is insufficient antecedent basis for this limitation in the claim. Perhaps, Applicant may overcome the rejection by replacing "patient" with animal model.

Claim 17 recites the limitation "the neural tissue" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting "the".

Claim 17 recites the limitation "the patient" in line 2. There is insufficient antecedent basis for this limitation in the claim. Perhaps, Applicant may overcome the rejection by replacing "patient" with animal model.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7 and 8 of U.S. Patent No. 6,767,564 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14-19 are generic to all that is recited claims 1-5, 7 and 8 of U.S. Patent No. 6,767,564 B2. That is, claims 1-5, 7 and 8 of U.S. Patent No. 6,767,564 B2 fall entirely within the scope of Claims 14-19, or in other words, Claims 14-19 are anticipated by claims 1-5, 7 and 8 of U.S. Patent No. 6,767,564 B2. Specifically, the method of claim 1 of the patent is a one-step method treating chronic neuroinflammation in a patient with neuroinflammatory autoimmune disease comprising administering to the patient an amount of Bowman Birk Inhibitor effective to reduce, inhibit or suppress the chronic inflammation.

The method for treating neuroinflammation in an animal model of an induced neuroinflammatory disease of instant Claim 14 requires administering an amount of Bowman Birk Inhibitor to an animal model in an amount effective to reduce, inhibit or suppress the chronic inflammation in an animal model, wherein neuroinflammatory has been induced therein the animal model. The Office notes that the specification of the instant application, as well as the patent specification, clearly defines an animal model of an induced neuroinflammatory disease as an appropriate species of patient which can be used in a method of treating neuroinflammation in a patient with neuroinflammatory autoimmune disease comprising the administration of an effective

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amount of a Bowman Birk Inhibitor to the patient, wherein the disease is Experimental Autoimmune Encephalomyelitis or Experimental Autoimmune Neuritis.

Thus, Claims 14-19 are deemed obvious variants of the limitations of the patented subject matter as per the supporting portions of U.S. Patent No. 6,767,564 B2 and the instant application.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

September 28, 2006